

SEP 16 2003

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510K Summary of Safety and Effectiveness
August 8, 2003
ArthroJet System with Cautery, TurboBurr, and Curette
A Modification to the
ArthroJet System with Cautery and TurboBurr

1. Sponsor Name

HydroCision, Inc
100 Burt Rd. Suite G01
Andover, MA 01810
Tel: 978-474-9300
Contact Individual: Debbie Iampietro

2. Device Name

Proprietary Name: ArthroJet System with Cautery, TurboBurr, and Curette
Common/Usual Name: Arthroscope and Accessories
Classification name: Arthroscope and Accessories

3. Identification of Legally Marketed Device

The modified HydroCision ArthroJet System with Cautery, TurboBurr, and Curette is substantially equivalent in intended use to the HydroCision ArthroJet System with Cautery and TurboBurr (K020688).

4. Device Description

The HydroCision ArthroJet System with Cautery, TurboBurr, and Curette consists of the reusable power control unit; a sterile, disposable pump cartridge and tubing assembly; and sterile, disposable handpieces with curette. It provides the same functions as the predicate upon which it is based. The handpiece includes the rotating burr, which is driven by a fluidjet driven rotor.

5. Intended Use

The HydroCision ArthroJet System with Cautery, TurboBurr, and Curette is indicated for orthopedic surgical procedures where the cutting and removal of soft tissue and the ablation and removal of hard tissue or bone is required, with control of bleeding during those procedures as needed. Specific functions include cutting, ablation and shaping of

soft tissue, and drilling, reaming, decorticating and smoothing of bone, cartilage and other bone related tissue in a variety of surgical procedures including open and minimally invasive spinal surgeries and small and large joint arthroscopic procedures.

6. Comparison of Technological Characteristics

Both the current and modified devices:

A. Have the same intended use

Both are intended for resection of tissue and bone in open and minimally invasive orthopedic procedures.

B. Use the same fundamental scientific technology

- a reusable power console unit
- fluid jet technology
- mechanical cutting using sharpened steel
- bipolar electrocautery
- a sterile, disposable pump cartridge, handpiece and tubing assembly comprised of two principal components:
 - a high pressure fluid conduit with integral fluidjet nozzle
 - a low pressure collection tube.

The differences between the proposed HydroCision ArthroJet System with Cautery, Turbo Burr and Curette and the current HydroCision ArthroJet System with Cautery and TurboBurr (K020688) are:

- Addition of Curette tool to the distal end of direct fluidjet handpieces

7. Performance Testing

Bench and cadaver testing were conducted to determine device functionality and conformance to design input requirements.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2003

HydroCision, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany
Hopkinton, MA 01748

Re: K032529

Trade/Device Name: HydroCision ArthroJet System with Cautery, TurboBurr and Curette
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: August 8, 2003
Received: August 21, 2003

Dear Ms. Iampietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

